HASS
CORPORATION

510(k) Summary
(K102305)

DEC - 3 2010

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 10/28/2010

1. Submission Sponsor

	Submitter
Name	HASS CORP.
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2. Submission Correspondent

LK Consulting Group
2341 W. Crescent Ave. #3,
Anaheim, CA 92801
Priscilla Chung
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Email: juhee.c@lkconsultinggroup.com

3. Device

Trade Name: HASS Zirtooth
Common Name: Dental Frame Material for Dental Prosthesis
Classification Name: Porcelain Powder for Clinical Us
Classification regulation: 21 CFR 872.6660

4. Predicate Device:

Vita In-Ceram YZ® Cubes for Cerec® (K022996), VITA Zahnfabrik GmbH & Co. KG

5. Description:

HASS Zirtooth is a zirconia porcelain product to be used to make the core of the all porcelain crown. It consists of ceramic blocks and corresponds to ISO 6872 Type 2 Class 1. This ceramic product provides the supporting structure for mounting the

ceramic restoration. The shelf life of the ceramic block is semi-permanent.

6. Indication for use:

HASS Zirtooth is indicated for use as a substructure for porcelain fused ceramic fixed dental restorations; namely crown, bridges, inlays, and onlays.

7. Safety and Effectiveness:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device as safe and effective as the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 5109(K) submission that the differences between the HASS Zirtooth and the predicate device do not raise any questions regarding its safety and effectiveness.

8. Physical Characteristics

The following properties were tested for the device according to ISO 6872 and 9693 and all the results met the test criteria.

- ISO 6872 - Uniformity, Extraneous Materials, Chemical Solubility, Flexural Strength, Radioactivity of dental ceramic and Flexural strength after the low temperature deterioration
- ISO 9693 - Coefficient of thermal expansion and Bonding strength with veneer ceramic

9. Conclusion

Based on the information provided in this premarket notification, HASS Zirtooth is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hass Corporation
C/O Ms. Priscilla Chung
LK Consulting Group
2341 W. Crescent Avenue #3
Anaheim, California 92801

DEC - 3 2010

Re: K102305
Trade/Device Name: Hass Zirtooth
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: October 13, 2010
Received: November 12, 2010

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): _____K102305_____

Device Name: Hass Zirtooth

Indications for Use:

HASS Zirtooth is indicated for use as a substructure for porcelain fused ceramic fixed dental restorations; namely crown, bridges, inlays, and onlays.

Prescription Use __√__ **AND** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEE DED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division Sign-Off)
Division of Anesthesiology, General Hos...
Infection Control, Dental Devices

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